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11-0900-17036-2

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE COMMISSIONER OF HEALTH

In the Matter of Bloomington Health Care and Rehab
Survey Date: December 9, 2005

RECOMMENDED DECISION

The above matter was the subject of an independent informal dispute resolution (IIDR) meeting conducted by Administrative Law Judge Barbara L. Neilson on April 12, 2006, at 9:30 a.m. at the Office of Administrative Hearings. The meeting concluded on that date.

Marci Martinson, Unit Supervisor, Division of Facility and Provider Compliance ("DFPC"), Minnesota Department of Health, 1645 Energy Park Drive, Suite 300, St. Paul, MN 55108-2970, appeared on behalf of DFPC. Mary Cahill also attended the meeting on behalf of the Department. Ellie Laumark, the supervisor of the team of surveyors, participated by telephone.

Randi Hansen, RN, C, Professional Services Consultant, Beverly Health Care, 22109 Woodland Lane, Rogers, MN 55374, appeared on behalf of Bloomington Health Care and Rehab ("the Facility"). The following persons made comments on behalf of the Facility: Joseph Gubbels, Executive Director; Mary Jasper, Director of Nursing; and Bruce Blythe, M.D., Medical Director of the Facility.

NOTICE

Under Minn. Stat. § 144A.10, subd.16(d)(6), this recommended decision is not binding on the Commissioner of Health. Under Department of Health Information Bulletin 04-07, the Commissioner must mail a final decision to the Facility indicating whether or not the Commissioner accepts or rejects the recommended decision of the Administrative Law Judge within 10 calendar days of receipt of this recommended decision.

Based upon the exhibits submitted and the arguments made, and for the reasons set out in the Memorandum that follows, the Administrative Law Judge makes the following:

RECOMMENDED DECISION

1. The citation for F-157 is supported in full.

2. The example of Resident #24 in the citation for F-282 is supported in full.

3. The example of Resident 24 in the citation for F-309 is supported in substance. The citation should be amended through a change in the severity assigned to the citation, from "J" to "D."

Dated: April 26, 2006

s/Barbara L. Neilson
_____
BARBARA L. NEILSON
Administrative Law Judge

Reported: Tape Recorded (Two Tapes, No Transcript Prepared).

MEMORANDUM

The Department of Health conducted a survey of Bloomington Health Care and Rehab in late 2005, which was concluded on December 9, 2005. Based on the survey, the Department issued several statements of deficiency. In this IIDR, the Facility is disputing all of the deficiency cited at F-157 (which involved Resident 24) and the example of Resident 24 included in the deficiencies issued at F-282 and F-309.[1] Because the facts relating to Resident 24's care are applicable to all three citations, those facts will be discussed first.

Resident 24

Resident 24 is an 88-year-old woman whose diagnoses include diabetes, hypertension, congestive heart failure, legal blindness, bilateral below-the-knee amputations, myocardial infarction, and atrial fibrillation.[2] She had stayed at the Facility on several occasions prior to October 2005, and was again admitted to the Facility from the hospital on October 28, 2005. She was readmitted to the hospital on November 4, 2005, for chest pain and early exacerbation of congestive heart failure.[3] She returned to the Facility's subacute unit on November 7, 2005, for rehabilitation which included physical therapy, occupational therapy, and speech therapy. The Resident's insulin orders were changed when she returned from her hospitalization on November 7, 2005.[4]

As of October 31, 2005, the Resident's plan of care indicated that Facility staff were to monitor for signs and symptoms of hyper/hypoglycemia; give Glucagon[5] as needed in accordance with the Facility's standing orders; and "notify MD PRN [as needed] of changes."[6] The Facility's standing orders for the administration of Glucagon indicated that it may be given one time for blood sugars less than 50 and then the physician is to be notified.[7] The Medication Record dated November 7-30, 2005, and the Admission Clarifications form dated November 18, 2005, instructed the Facility staff to call the Resident's primary care physician (Dr. Schaffer) when blood sugars were less than 60.[8] The Resident and her daughter expressed their wishes that the Resident be considered "full code" (as opposed to "do not resuscitate").[9] The minimum data set assessment dated November 3, 2005, gave Resident 24's cognition status as a "1," which means that she can make decisions with modified independence, having some difficulty only in new situations.[10]

The Facility routinely monitored the Resident's blood glucose four times a day. Because Resident 24 was on a sliding scale for insulin, her dosages were adjusted at least four times a day based on her current blood glucose levels.[11] The Facility also monitored the Resident's blood glucose if she was experiencing symptoms. During the last few days of November 2005, Resident 24 developed a urinary tract infection and her food intake decreased due to poor appetite. The Resident's daughter asked the Facility to check blood glucose levels at 2:00 a.m. during the period of illness because the Resident has a history of worsened glucose control during illness. The request was honored beginning December 1, 2005.[12]

When the Resident was first admitted to the Facility in October 2005, she was on a consistent carbohydrate diet. According to the Facility's dietary manual, this diet should be used for "stable" diabetics.[13] When the Resident returned to the Facility from the hospital on November 7, 2005, this diet was no longer considered appropriate because of the Resident's decreased meal intake.[14] The Resident was assessed by a Registered Dietitian on November 2, 2005, with a follow-up on November 9, 2005, after she returned from the hospital. The dietitian assessed her weight status, her estimated nutrient needs, and meal intake.[15] The dietitian also made additional notations to the Resident's chart on November 2 about the Resident's intake at meals being less than 75% and the need for monitoring and possibly requesting Med Pass for added calories.[16] On November 9, the dietitian added another note to the Resident's chart finding the new diet order following hospitalization to be appropriate and recommending Med Pass when meal intake was less than 50%,[17] and also contacted Dr. Schaffer to seek approval of the recommended diet and use of Med Pass.[18]

On December 7, 2005, at 2:00 p.m., Resident 24's daughter approached one of the surveyors with concerns about her mother. Her primary concern was the lack of monitoring of her mother's food intake as it related to her diabetes. The daughter told the surveyor that she felt that Resident 24 was not getting proper bedtime snacks, her incidents of low blood glucose were increasing, and some of the meals offered by the Facility were of poor quality. She also said that snacks were not labeled for her mother or for diabetics and were not always brought into the room. She told the surveyors that she would take a snack from the snack cart in the hall in the evenings and give it to her mother. Because the Resident was blind and a double amputee, the Resident would not have been able to access snacks in the hall on her own. Resident 24's daughter told the surveyors that her mother had had several episodes of low blood glucose, the more recent ones occurring in the early morning hours. She said that these increased episodes had left her mother feeling washed out and lethargic, and had delayed her healing process. She also said that it was hard on Resident 24 and that, with each episode, it took Resident 24 a little longer to recover. The daughter acknowledged that Resident 24 had had episodes of low glucose at home when she was ill but asserted that they were never this frequent. The Resident's daughter told surveyors that she was afraid to leave her mother alone at the Facility because she was concerned that her mother's blood sugar might drop and she might not be able to call for help. She told the surveyors that she had expressed her concerns several times to staff members.[19] The Facility submitted affidavits of numerous staff members indicating that the Resident's daughter had not expressed concerns to them about the food being inadequate, failure

to provide proper bedtime snacks, concerns about increasing incidents of low blood glucose, or concerns about the Resident's safety.[20]

The surveyors observed that there were no labels on any of the evening snacks that identified the diabetics to ensure that they received the snacks necessary to regulate their blood sugars.[21] The Facility's documentation of Resident 24's meal intake showed that she ate "none to very little" of the evening snack 32 out of 37 days.[22] Some other residents told the surveyors that they were unaware of the availability of evening snacks or that they didn't have snacks until the surveyors arrived.[23]

At approximately 4:10 p.m. on December 7, 2005, the Resident's daughter called a surveyor into her mother's room while she was again experiencing symptoms of low blood glucose.[24] The surveyor observed the Resident having hypoglycemic symptoms. The daughter had also alerted Facility staff and nursing staff responded appropriately, providing orange juice to the Resident and remaining with the Resident. The Resident's blood glucose level at this time was 62. The nurse stated that she would call the doctor for adjustment to Resident 24's insulin orders. The surveyors spoke with the Director of Nurses at 4:30 p.m. to tell her of conversations with the Resident's daughter, relay how upset the daughter was, and inform her of the Resident's episode of low blood sugars. The Director of Nursing stated that she was not previously aware that the daughter was unhappy with the care of Resident 24.[25]

The nursing notes and other records relating to the Resident confirmed that Resident 24 had low blood glucose on several occasions during her stay at the Facility. Her blood glucose level was under 60 on seven occasions, three of which occurred after the November 18 order was received requiring the Facility to notify Dr. Schaffer of blood sugars below 60. On October 29, 2005, Resident 24 was lethargic and sweating at 5:30 p.m. and her blood glucose level was 59. She was given Glucagon. Upon recheck ten minutes later, her blood sugar was 57, and she was given juice and oral glucose gel. Her blood sugar thereafter rose to 81 and 123, and the nursing notes indicate that her physician was contacted and updated on her condition.[26] On October 31, 2005, the Resident's blood glucose level was 59 at 7:30 a.m. She was given juice and her glucose level after breakfast was 224.[27] On November 11, 2005, at 1:26 a.m., the Resident complained of sweating, her blood glucose level was 57, and she was given juice.[28] On November 17, 2005, the Resident complained that she was not feeling well at approximately 3:00 a.m., her blood glucose level was found to be 54 and she was given juice, crackers, and a banana. Upon recheck, her blood glucose was noted to be 128.[29] On November 22 , 2005, the Resident refused insulin and her blood glucose level was 56 at 5:30 p.m. No interventions were recorded in the chart.[30] On November 30, 2005, at 2:00 a.m., the Resident's blood glucose level was 47. She was given juice and a snack. Upon recheck, her glucose level had risen to 100.[31] On December 6, 2005, her glucose level was 61 at 2:00 a.m. and she was fed juice and a sandwich.[32] On December 7, 2005, at 2:30 a.m., the Resident was very lethargic and difficult to arouse. Her blood glucose level was 48. She was given orange juice and Glucose gel, continued to be lethargic, and was administered Glucagon at 3:15 a.m. By 4:00 a.m., her blood sugar had risen to 228.[33] Finally, on December 7, 2005, at 4:00 p.m., her

blood glucose level was 62. Facility staff gave her orange juice and a snack. By 4:30 p.m., the Resident's blood glucose had risen to 80, and by 7:30 p.m. it was 140.[34]

The Facility sent a fax to Dr. Schaffer on December 7, 2005, at 4:35 p.m. and also called him.[35] The fax included a request for the doctor to review blood glucose levels, informed him of increased episodes of low blood glucose, and asked whether there was something they could do to help regulate her blood sugars more, such as specific snack times. The memo to Dr. Schaffer included a reference to the Resident's full code status, a suggestion that the Resident may need hospitalization for diabetes regulation, and a statement that the Resident's daughter was extremely upset.[36] The fax inadvertently neglected to include the information about the Resident's low blood sugar of 48 on December 7, 2005, at 2:30 a.m., did not contain all of the information regarding the Resident's history of low blood sugars, and did not indicate that the Resident had received Glucagon the morning of December 7, 2005, after her blood glucose was 48. Facility staff contacted the Medical Director (Dr. Blythe) for orders to cover until Dr. Schaffer could respond, and Dr. Blythe changed the Resident's insulin orders.[37] A response from Dr. Schaffer was received during the evening of December 7, 2005.[38] Dr. Schaffer immediately changed the Resident's insulin regimen and also changed the directions for the sliding scale to take into account whether the Resident had eaten less than 75% of her meal. He further noted that the Resident "[h]as labile diabetes [subject to change or instability]. Hospitalization to regulate DM [diabetes myelitis] not an option."[39]

Because the Resident's daughter had already left the Facility for the day by the time the fax was received, the Director of Nursing decided to tell her about Dr. Schaffer's response after she returned to the Facility the next morning. During the morning of December 8, 2005, one of the surveyors reviewed Dr. Schaffer's order and asked the Director of Nursing whether the Resident or daughter had been informed of the order. The Director stated that she intended to inform them but had not yet done so since the daughter had not arrived.[40] Later that morning, when Resident 24 and her daughter had still not been informed by the Facility of Dr. Schaffer's order, the surveyor told them about it at the request of the daughter.[41] Resident 24 told the surveyor that she wanted to live as long as she could, and both Resident 24 and her daughter stated their belief that Dr. Schaffer was "giving up on" Resident 24. They reiterated their desire to continue full code measures. They also decided that they would no longer use Dr. Schaffer as the Resident's primary care physician.[42]

The only documented occasions when Facility staff notified the Resident's physician regarding Resident 24's low blood sugar were on October 29, 2005, and again on December 7, 2005, after the surveyor spoke to the Director of Nurses at approximately 4:30 p.m. to inform her of conversations with the Resident's daughter and to relay how upset she was. The Facility's Director of Nursing indicated during her interview with surveyors that she was sure that the nurses did notify the physician on other occasions but they probably did not chart it.[43]

Resident 24 no longer resides at the Facility. She was discharged to home with her daughter on December 16, 2005, after successful rehabilitation.[44] She sought to be readmitted to the Facility in January of 2006, but the Facility was unable to accommodate her.[45]

As described below, the Department issued citations to the Facility in connection with Resident 24 under F-157, F-282, and F-309. Each will be discussed in turn.

Citation F-157

Federal regulations require that the resident's physician and family must be informed immediately if there is "[a] "significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications)" or "[a] need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment)."[46]

This deficiency was issued at a scope and severity of G, isolated, actual harm. Chapter 7 of the State Operations Manual indicates that IIDRs may not be used to dispute scope and severity unless it rises to the level of IJ or substandard quality of care.

The DFPC asserts that this deficiency is justified by the Facility's failure to notify the Resident 24's physician of her multiple episodes of low blood glucose. The physician was not notified of several episodes of low blood sugar with symptoms, was not notified when the Resident's blood glucose dropped below 60 as required by his orders, and was not notified after the Resident received Glucagon as required by the house standing orders. Without this knowledge, the DFPC contends that the physician did not have the information to determine whether or not the Resident's insulin regimen was appropriate and the Resident continued to experience the hypoglycemic episodes with increasing frequency. The DFPC emphasizes that the physician changed the Resident's insulin regimen as soon as he was made aware of the multiple episodes of low blood sugars.

The Facility disputes the factual information on which the surveyors relied. The Facility asserts that, during the Resident's 39 days in the facility from admission to December 7, she had only 2 readings under 60 in the regular QID checks. One of these was on October 29, 2005, and the other was on November 21, 2005. Both of these episodes were treated with juice, and the subsequent readings were 283 and 164 respectively. The Facility admits that there were three other readings under 60 in which the blood glucose checks were done as additional monitoring in the middle of the night (on November 11, November 17, and December 7). In each instance, the Resident was given juice and/or a snack and was then rechecked and monitored. Dr. Blythe and Dr. Godsall expressed their opinions that the Resident did not sustain any harm and the Facility handled the episodes of hypoglycemia appropriately and successfully.[47] 0

The Facility points out that occasional episodes of low blood sugar were to be expected in light of the Resident's intensive therapy for diabetes and that some increase in incidents of low blood sugar is a natural part of the aging process. The Facility also argues that high blood sugar is generally considered to be the predominant cause of diabetic complications. The Facility emphasizes that its nursing staff responded appropriately to increase the Resident's blood sugars, and that her low blood glucose levels typically rose rapidly after such treatment. The Facility also emphasizes that the Resident was able to recognize the signs of hypoglycemia early when the symptoms were mild and would inform staff if that occurred.[48]

The Facility's Director of Nursing stated during her interview with surveyors and at the IIDR that she is sure that Facility staff nurses notified the physician of the low readings but they probably failed to document that notification on the patient's chart. However, none of the individual staff nurses has provided any support for that view, and there is no record of any change in insulin regimen or other response from the physician to any such notification. The Facility also contends that the episodes of low blood glucose were not a significant change because the Resident had experienced them even while living with her daughter prior to her nursing home stay, and hospital records[49] from her hospitalization in October 2005 show that some incidents of low blood sugar also occurred at that time. However, the Resident's daughter told the surveyors that the episodes had never been as frequent as they were in the Facility, and there is no evidence to the contrary. Moreover, the hospital records were not available either to the surveyors or to the Facility before the conclusion of the survey.

Based upon the evidence submitted, it appears that there was, in fact, a significant change in physical status and clinical complications for the Resident given the increasing frequency of her low blood glucose episodes during the period of November 30 to December 7. The Resident's blood glucose level was below 50 on two occasions during this period, and between 61 and 63 on four other occasions.[50] While this increase in frequency may have been linked to her urinary tract infection during the same time frame, it is, nevertheless, a significant increase within the meaning of 42 C.F.R. § 483.10(b)(11)(i)(B). During episodes of low blood glucose, Resident 24 experienced symptoms such as lethargy, sweating, and a general feeling of ill health, and required treatment.[51] In addition, it appears that there was a need to alter treatment significantly in view of the low blood glucose episodes within the meaning of 42 C.F.R. 483.10(b)(11)(i)(C), as supported by the immediate change ordered by Drs. Blythe and Schaffer in the Resident's insulin and dosing schedule once they were informed of the episodes. Although the DFPC agreed that nursing staff in the Facility responded appropriately to treat the Resident's low blood sugars, there is no supporting documentation that staff ensured that Dr. Schaffer was notified of significant changes, (which he had defined to include blood sugars under 60 by virtue of his November 18 order) and those requiring the administration of Glucagon. The physician's orders did not indicate that the results of additional blood sugar monitoring performed by the Facility were somehow to be considered exempt from these orders. The citation for this deficiency is supported by the record.

Citation F-282

The federal regulation on which this citation is based requires that "[t]he services provided or arranged by the facility must . . . [b]e provided by qualified persons in accordance with each resident's written plan of care."[52] In this instance, the Resident's plan of care included the following interventions: "Monitor for s/s [signs and symptoms] of hyper/hypo glycemia," "Glucagon PRN [as needed] per SHO [standing house orders], and "Notify MD PRN [as needed] of changes."[53] This deficiency was also issued at a scope and severity of G, isolated, actual harm.

As discussed above, there is sufficient evidence to support the issuance of this citation. The plan of care was not properly implemented because there is no convincing evidence that the physician was notified as needed of changes. Dr. Schaffer's order of

November 18 set a parameter for notification of low blood sugar that was not followed by Facility staff, and Facility staff also failed to notify Dr. Schaffer that Glucagon was administered during the early morning hours of December 7, 2005. When the care plan directed that certain levels should trigger a call to the physician, that plan should have been followed. The care plan did not say that the physician should be notified only if there were several consecutive readings below 60 or only if one of the four "routine" glucose checks revealed a level below 60. Accordingly, the Facility should have notified the physician whenever the Resident's blood glucose level at any time of day or night was under 60. This citation is supported by the record.

Citation F-309

The federal regulations governing this area specify that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."[54] The interpretive guidelines indicate that the facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of the resident's right to refuse treatment, recognized pathology, and the normal aging process. The term "highest practicable" is defined as the highest level of functioning and well-being possible, limited only by the individual's presenting functional status and potential for improvement or reduced rate of functional decline.[55] The guidelines state that, where there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable, and may only find unavoidable decline if an accurate and complete assessment was performed, the care plan was implemented consistently and based on information from the assessment, and the results of the interventions were evaluated and the interventions were revised as necessary.

Although this deficiency was issued for multiple residents, the Facility is disputing only the example of Resident 24 in this IIDR review. The DFPC issued this deficiency tag based in part on its conclusion that the Facility failed to provide diabetic management and timely interventions and services to Resident 24 and failed to intervene to protect resident choice for Resident 24 in connection with a physician's order conflicting with the resident's wishes for hospitalization if necessary. Resident 24 was found to be in an Immediate Jeopardy situation based upon the DFPC's view that the Facility failed to adequately monitor all aspects of her diabetes, failed to consistently inform the physician regarding increasing episodes of low blood sugars, and failed to clarify a contradictory order regarding the Resident's code status. Because of the example of Resident 24, the deficiency was issued at a scope and severity level of J (immediate jeopardy that was isolated).

As an initial matter, the inclusion of the example of Resident 24 in the citation for F-309 is found to be supported in substance. As detailed above, the Facility failed to consistently inform the Resident's physician of all of the Resident's episodes of low blood sugar despite the directive in the care plan to notify the physician of changes as needed, the physician's November 18 order to notify him if blood sugar dropped below 60, and the Facility's standing order requiring notification when Glucagon was administered. The Facility also did not bring the Resident's increasing episodes of low blood sugar during the period of November 30 – December 7 to the physician's

attention until 4:35 p.m. on December 7. The Resident experienced several episodes of hypoglycemic symptoms as a result, and thus sustained some harm, although it was very limited in duration and treated by prompt Facility intervention. Although the Resident ultimately had the right to choose what she did and did not want to eat, and there is some support for the view that dietary restrictions are not warranted for long-term care residents,[56] the Facility's failure to plan and offer high quality evening snacks for the Resident despite its knowledge that she was typically eating little or nothing in the evening and was experiencing low blood sugar particularly during the night or in the early morning potentially put Resident 24 at risk of experiencing future hypoglycemic episodes. The Facility thereby failed to provide the necessary care and services for the Resident to attain or maintain the highest practicable well-being, in accordance with her assessment and plan of care, and the citation as to Resident 24 is found to be supported in substance.

The other assertions made by DFPC with respect to Resident 24 are not supported. The Facility in fact monitored the Resident's blood sugar levels as part of its routine practice, added an additional check in the early morning hours at the request of the Resident's daughter, responded appropriately and promptly to episodes of hypoglycemia, adjusted the Resident's sliding scale insulin doses, monitored the Resident's food intake, provided her with a liberalized diet in an attempt to increase her food intake (consistent with guidelines of the American Dietetic Association and American Diabetes Association), and otherwise provided adequate care and services to the Resident.

The DFPC maintains that the Facility's failure to provide timely interventions in diabetic management for Resident 24 in conjunction with its failure to protect the client's choice to be hospitalized if necessary resulted in an immediate jeopardy situation. According to Chapter 7 of the State Operations Manual, the Facility has the right to dispute during an IIDR both the deficiency itself and the scope and severity of a deficiency issued at the level of immediate jeopardy (IJ).[57] Immediate jeopardy is defined as a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.[58] Appendix Q of the State Operations Manual clarifies that either actual harm or the potential for harm to one or more individual may constitute IJ; only one individual needs to be at risk; serious harm, injury, impairment, or death does not have to occur before considering IJ, but the high potential for these outcomes to occur in the very near future also constitutes IJ; and psychological harm is as serious as physical harm.[59] If the team identifies an IJ situation, Appendix Q indicates that the team must consider whether the Facility either created or allowed a situation to continue which resulted in serious harm or the potential for serious harm, injury, impairment, or death to individuals, and whether the Facility had an opportunity to implement corrective or preventive measures.[60] Appendix Q identifies various "triggers" or situations that will cause the surveyor to consider if further investigation is needed to determine the presence of IJ, including "lack of supervision for individual with known special needs," "failure to carry out doctor's orders," "failure to adequately monitor and intervene for serious medical/surgical conditions," and "lack of diabetic monitoring resulting or likely to result in serious hypoglycemic or hyperglycemic reaction."[61]

The IJ was issued based on several factors, including the following: (1) the Resident had multiple episodes of low blood sugar that required treatment by staff; (2) the Resident had required a Glucagon injection on 12/7/05 and the physician had not been notified; (3) evening snacks were not routinely offered and there was no planned evening snack for the Resident, who was a "brittle" diabetic and was having episodes of low blood sugar during the night or in the early morning; (4) the Facility was aware of the Resident's low blood sugars as evidenced by the nursing notes; (5) the Facility was aware the Resident wasn't consuming enough evening snacks as evidenced by the meal intake record; and (6) after the surveyor began asking questions, the Facility finally notified the physician; however, the physician wrote an order that could be interpreted to conflict with the Resident's wishes regarding treatment and hospitalization, and the Facility did not clarify the order.

The Facility argued that the IJ was inappropriate for a number of reasons. Bruce Blythe, M.D., the Facility's Medical Director and a partner of Dr. Schaffer, wrote a written report dated December 14, 2005, in which he indicated that he had reviewed the glycemic control of the Resident and found no periods of extraordinary hyperglycemia and no periods of symptomatic hypoglycemia (loss of consciousness, prolonged tremor, seizure, slurred speech, sweating, or nausea). Rather, he found the record of glucose values to demonstrate acceptable control of the Resident's diabetes. Although he admitted that the glucose values varied somewhat more between December 1 and December 8, when the Resident's oral intake was variable due to a concurrent urinary tract infection, Dr. Blythe determined that the sliding scale insulin seemed to maintain the values within a safe range. In his opinion, the Resident did not sustain any harm related to poor glycemic control, was not placed in a position of harm or potential harm related to poor glycemic control, responses to episodes of hyperglycemia and hypoglycemia were appropriate and successful, and physician notification and order implementation was appropriate.[62] Dr. Blythe, who has known the Resident for approximately 15 years and is now the Resident's primary care physician, indicated during the IIDR meeting that both the Resident and her daughter were told that hypoglycemia would be a consequence of more aggressive medical treatment of her diabetes, but they still wanted to take that approach. He indicated that the Resident continued to experience episodes of mild hypoglycemia even after her insulin regimen was changed to long-lasting insulin. Dr. Blythe emphasized that the Resident's hypoglycemic episodes between November 30 and December 7 were relatively mild except for the moderate episode during the early morning hours of December 7, the Resident responded to treatment, and she did not experience any long-lasting or prolonged physical harm.

The Facility also submitted a letter from J. Ward Godsall, MD, during the IIDR. Dr. Godsall, who is an endocrinologist, indicated that he reviewed records given to him by the Facility, including the Resident's diabetic flow sheets with glucose measurements, and concluded that the Resident's care at the Facility was appropriate, she was managed well in the Facility, and she did not require hospitalization. Dr. Godsall stated that levels of hypoglycemia reaching 50 and 60 mg/dl "is not uncommon when one is trying to control the glucose, and, if treated appropriately, is not dangerous. The patient recognizes the symptoms of her hypoglycemia and the nursing staff has responded to the episodes appropriately. As a result she did not go into

hypoglycemic coma." Dr. Godsall does not feel that the Resident was in imminent danger under these circumstances.[63]

The Facility also disagreed with the DFPC's view that the Resident was placed in immediate jeopardy by virtue of Dr. Schaffer's December 7 faxed order advising that hospitalization to regulate the Resident's diabetes was "not an option." During the surveyors' interview with Dr. Blythe, the Facility's Medical Director, on December 8, 2005, he told them that, regardless of Dr. Schaffer's faxed order, the Facility would have followed the family's wishes regarding hospitalization of the Resident.[64] In addition, Karen Meyer, LPN, and Miranda Cosgrove, LPN, both submitted statements indicating that they understood Dr. Schaffer's December 7 faxed order to mean that the Resident should not be hospitalized for management of diabetes at that time but not to mean that the Resident could never be sent to the hospital for any reason. Both said that they would have continued to send the Resident to the hospital if some other situation had arisen.[65] The Director of Nursing also submitted a statement and indicated during the IIDR meeting that she would instruct staff to follow a resident's full code status as opposed to any contradictory orders.[66] Moreover, Dr. Schaffer clarified in a fax dated December 9, 2005, that his December 7 order "pertained exclusively to [the Resident's] bouts of hypoglycemia, not as a general order. Changing her insulin and monitoring closely should be sufficient to avoid further episodes." He was critical of the surveyors' "inflammatory reaction" to his fax and the "serious and erroneous conclusions" that were drawn.[67]

Based upon all of the evidence submitted in connection with the IIDR, the Administrative Law Judge recommends a reduction in the severity of this citation from "J" (IJ to resident's health or safety, isolated) to "D" (no actual harm with potential for more than minimal harm that is not IJ, isolated). The Resident was able to recognize the symptoms of hypoglycemia, and the Facility responded promptly to treat those symptoms. Although the Resident suffered some unpleasant symptoms associated with these hypoglycemic episodes, there is no evidence that she experienced any actual, prolonged harm or that the Facility's failure to notify the physician was likely to cause serious injury, harm, impairment, or death. These episodes apparently had a limited consequence for the Resident, since she was able to return to her daughter's home on December 16, 2005. The Administrative Law Judge also does not agree that Dr. Schaffer's December 7 fax supports assignment of a severity level of "J." In the Judge's view, Dr. Schaffer's fax could not reasonably be construed to constitute a conflicting order regarding the Resident's code status or an order that would prevent her hospitalization, as alleged by the DFPC. The Facility representatives indicated that they merely interpreted Dr. Schaffer's faxed message to mean that he did not agree that the Resident should be hospitalized at that particular time based upon the specific information presented in the Facility's message to him, and not to represent an order attempting to override the Resident's full code status. Dr. Blythe, the Facility's Medical Director, indicated that, if an issue had arisen, there was no possibility that the Facility would not have hospitalized a full code resident. If the staff had had any question, they would have called Dr. Blythe. There is no evidence that any member of the Facility's staff interpreted Dr. Schaffer's order to be a general directive that the Resident should never be hospitalized. Thus, it is clear that the Resident continued to be considered "full code" and would have been hospitalized if warranted or if she or her daughter had

so requested. Under the circumstances, the failure of the Facility to take immediate action to clarify the fax does not provide support for an IJ severity level.

In summary, the example of Resident 24 in the citation for F-309 is found to be supported in substance. The citation should be amended through a change in the severity assigned to the citation, from "J" to "D."

B.L.N.

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[1] March 20, 2006, letter to Joseph Gubbels from Marci Martinson, attached to April 4, 2006, letter to Administrative Law Judge from Ms. Martinson.
[2] Exs. L-1, Q-3.
[3] Ex. L-35.
[4] Exs. G-5, L-36.
[5] Dr. Blythe explained during the IIDR meeting that Glucagon is a naturally occurring hormone which is administered by injection in order to raise a resident's blood sugar.
[6] Ex. L-20.
[7] Ex. L-84.
[8] Exs. L-68, L-58.
[9] Exs. L-25, L-58, L-66, N-15.
[10] Ex. L-3.
[11] *See, e.g.,* Ex. R-7.
[12] Ex. R-2.
[13] Ex. M-1.
[14] Exs. Q-8, Q-9.
[15] Exs. Q-5, Q-6.
[16] Ex. Q-7.
[17] Ex. Q-8.
[18] Ex. Q-9.
[19] Exs. I-3, N-2, N-3b, N-4b, N-5a, N-5b, N-6a.
[20] See Affidavits of Gollnick, Stevek, Bundy, Persaud, Meyer, Johnson, Norland, Englund, Bartz,
[21] Exs. G-9 through G-10, N-1b.
[22] Ex. L-82.
[23] Exs. N-1b, N-19, N-22a..
[24] Ex. N-7a.
[25] Ex. N-7a, N-7b
[26] Ex. L-30.
[27] Ex. R-3. The nursing notes for this episode are not included in the IIDR exhibits, but it is reflected in the Blood Sugar Readings chart at Ex. R-3. This incident of low blood sugar was not mentioned by the DFPC in the summary it prepared for the IIDR.
[28] Ex. L-40.
[29] Ex. L-43.
[30] Ex. L.45. Ex. R-3 shows this incident occurring on November 21, not November 22.

[31] Ex. R-3. The nursing notes for this episode are not included in the IIDR exhibits but it is reflected in the Blood Sugar Readings chart at Ex. R-3. This incident of low blood sugar was not mentioned by the DFPC in the summary it prepared for the IIDR.
[32] Ex. L-54.
[33] Ex. L-54.
[34] Ex. L-56.
[35] Exs. L-26, L-55.
[36] Ex. L-26.
[37] Exs. R-9, R-11.
[38] Exs. L-27, N-8a.
[39] Ex. L-27 (emphasis in original).
[40] Ex. N-9a.
[41] Exs. N-9a, N-9b. The DFPC contends that the surveyor first spoke to the DON at 8:30 a.m. and later told the Resident and her daughter about Dr. Schaffer's order at 10:20 a.m. The Director of Nursing indicated during the IIDR meeting that the time lapse between her initial conversation with the surveyor and the surveyor's conversation with the Resident and her daughter was only approximately five minutes.
[42] Exs. N-9b and N-10a.
[43] Ex. N-7b.
[44] Exs. G-5, Q-1.
[45] Ex. Q-2.
[46] 42 C.F.R. § 483.10(b)(11)(i)(B) and (C).
[47] Ex. G-4.
[48] Ex. R-5.
[49] Ex. Q-3 (Abbott Northwestern admission notes relating to the Resident's October 4, 2005, hospitalization indicate that the Resident's daughter said that she had been adjusting the Resident's dose of Lantus downward "since the patient is having low blood sugars anywhere from 50 to 90 at 2 o'clock in the morning"). It is unclear what period of time the daughter was referencing, or how frequently this occurred.
[50] See Ex. R-3.
[51] According to *Guidelines for Diabetes Care in Long-term Care Facilities* prepared through a collaborative effort of Minneapolis/St. Paul Diabetes Educators, Long-term Care Organizations, Gerontology Practitioners, and the Minnesota Diabetes Control Program, Fourth Edition, hypoglycemia is defined as blood glucose less than 80 mg/dL (with or without symptoms) or blood glucose below goal range set by the primary care provider. The Guidelines indicate that lack of detection of hypoglycemia can lead to "severe symptoms (e.g. seizures or unconsciousness). Immediate treatment relieves symptoms and prevents a decline in condition." Ex. P-2. To prevent hypoglycemia, the Guidelines recommend, among other things, that causes be identified, a change in the treatment plan be initiated when two to three episodes occur in a week, and bedtime snacks be provided as late as comfortably possible for the resident. Ex. P-4. In addition, the DFPC indicated during the IIDR that there has been one death of a hospital patient in Minnesota related to hypoglycemia.
[52] 42 C.F.R. § 483.20(k)(3)(ii).
[53] Ex. L-20.
[54] 42 C.F.R. § 483.25.
[55] Ex. F-1.
[56] The Facility submitted materials supporting the view that dietary restrictions for long-term care residents "should be discouraged unless significant health gains can be expected. Residents benefit greatly when diets prescribed for them resemble the diets they could be expected to follow if they were in their own homes." Ex. T-5. The Facility also pointed to research reported in the Journal of the American Dietetic Association indicating that the imposition of dietary restrictions on elderly residents with diabetes is not warranted and "it is preferable to make medication changes rather than implement food restrictions in order to control the blood glucose." Ex. T-6.
[57] Ex. A-2.
[58] 42 C.F.R. § 489.3; *see also* Appendix Q of the State Operations Manual, Ex. E-2.
[59] Ex. E-2 through E-3.
[60] Ex. E-3 through E-4.
[61] Ex. E-4 through E-6.

[62] Ex. R-2.
[63] Ex. U.
[64] Ex. N-14.
[65] Affidavit of Karen Meyer; Affidavit of Miranda Cosgrove; see also Ex. T-7.
[66] Affidavit of Mary Jasper.
[67] Ex. T-9.